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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,792	11/10/2005	Giuseppe Pier Pelicci	LEDER-0014	4653

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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
08/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/529,792	PELICCI ET AL.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/29/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) *12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-11 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/5/09* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4-19 and 21-23 are all the pending claims for this application.

2. Claims 2 and 20 were cancelled and Claims 1, 9-11 and 21-23 were amended in the Response of 4/29/09.

3. Claims 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

4. The non-elected species for a disorder in Claim 6 are withdrawn as indicated in the Office Action of 5/1/08.

5. Claims 1, 4-11 and 21-23 are all the pending claims under examination.

6. Applicants amendments to the claims have necessitated new grounds for objection and rejection. The finality of this Office action is withdrawn.

Information Disclosure Statement

7. The IDS of 2/5/09 has been considered and entered. The initialed and signed 1449 form is attached.

Withdrawal of Objections

Oath/Declaration

8. The objection to the oath/declaration because: It was not executed in accordance with either 37 CFR 1.66 or 1.68 is withdrawn.

Under MPEP 201.06(c) “The patent statute and rules of practice do not require that an oath or declaration include a date of execution, and no objection should be

made to an oath or declaration because it lacks either a recent date of execution or any date of execution"; and MPEP 602.05 states "The Office no longer checks the date of execution of the oath or declaration and the Office will no longer require a newly executed oath or declaration based on an oath or declaration being stale (that is when the date of execution is more than 3 months prior to the filing date of the application) or where the date of execution has been omitted."

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, second paragraph

9. The rejection of Claims 9-11 and 20-23 for the recitation "a sample derived from tissue" in Claims 9-11 is withdrawn in view of the amendment of the claims to recite "obtained from" in the Response of 4/29/09.

Claim Rejections - 35 USC § 103

10. The rejection of Claims 1, 2 and 6-11 under 35 U.S.C. 103(a) as being unpatentable over Butler et al. (Clin. Can. Res. 7:962-970 (2001); cited in the IDS of 3/30/05; Butler I) in view of Marks et al. (Nature Reviews Cancer 1:194-202 (2001); cited in the IDS of 3/30/05) and Komatsu (US 20040198959; published 10/7/04; filed 3/13/02) is withdrawn.

Applicants have amended generic claims 1 and 11 in the Response of 4/29/09 to recite the monoclonal antibodies T25 and T52, which are not disclosed in any of the cited art references.

Rejections Maintained

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. The rejection of Claims 11 and 21-23 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained. See MPEP § 2172.01. The omitted steps are: the relationship between steps a) and b) of Claim 11. Is the histone acetylation level directly correlated with the extent of the antibody binding to the sample in the contacting step of b) or is the antibody used to immunopurify the acetylated histone which level is then quantitated by some other means? Further it is not clear what is meant by the sample level of histone acetylation being a “lower level” than the reference sample in order to correlate the HDAC treatment responsiveness to the classification of the tumor.

Applicants have not responded to this aspect of the rejection in their Response.

New Grounds for Objection

Claim Objections

12. Claims 9 and 10 are objected to because of the following informalities: Claims 9 and 10 have been amended to recite “and method comprises processing”. In order to substantially improve claim form, it is suggested that the noted phrase be amended to recite, *e.g.,* " and said method comprises processing”.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 4-11 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1 and 4-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the relationship between steps a) and b) of Claim 1. Is the histone acetylation level directly correlated with the extent of the antibody binding to the sample in the contacting step of b) or is the antibody used to immunopurify the acetylated histone which level is then quantitated by some other means? Is the HDAC inhibitor the same as the T25 or T52 antibody or are the antibodies only used to quantify the level of histone acetylation in the sample? Further it is not clear what is meant by the sample level of histone acetylation being a "lower level" than the reference sample in order to correlate the level with: "diagnosing a disorder *with* an HDAC inhibitor" (see preamble); "prognosing a treatment of a disorder *with* an HDAC inhibitor" (see preamble); and treating a disorder with an HDAC inhibitor.

Applicants should consider amending the preamble of Claim 1 to clarify the subject matter for this method and amending the body of claim 1 to clarify the relationship of the reagents used in the method steps to the HDAC inhibitor. Otherwise,

the ordinary artisan could not determine the metes and bounds of the subject matter for this method.

b) Claim 10 is indefinite for the recitation “a further sample obtained from tissue affected by the disorder which has been contacted with an HDAC inhibitor” because it is not clear if the method step requires that the sample is contacted with an HDAC inhibitor or that the tissue (from which the sample is obtained) has been contacted with an HDAC inhibitor. Also, it is not clear if the HDAC inhibitor of Claim 10 is the same or different from the HDAC inhibitor of Claim 1.

c) Claim 11 recites the limitation “said HDAC inhibitor.” There is insufficient antecedent basis for this limitation in the claim.

d) Claim 21 recites the limitation "wherein the conjugate comprises a radioactive compound". There is insufficient antecedent basis for this limitation in the claim.

e) Claim 22 recites the limitation “wherein the conjugate comprises a chemotherapeutic or cytotoxic agent.” There is insufficient antecedent basis for this limitation in the claim.

f) Claim 23 recites the limitation “wherein the conjugate is released by proteolytic cleavage.” There is insufficient antecedent basis for this limitation in the claim.

Conclusion

14. No claims are allowed.

15. The monoclonal antibodies, T25 and T52, and the hyrbidoma from which each antibody is produced, are novel and non-obvious.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNN BRISTOL whose telephone number is (571)272-6883. The examiner can normally be reached on 8:00-4:30, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/
Examiner, Art Unit 1643
Temporary Full Signatory Authority